

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte KAREN L. BRIEGS, DAVID DETORO,  
ANDREW KEIM and JEAN-LOUIS SAILLOT

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Appeal No. 2005-0617  
Application No. 09/655,667

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MAILED

JUN 06 2005

U.S. PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

ON BRIEF

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Before SMITH, JERRY, RUGGIERO, and DIXON, Administrative Patent Judges.

SMITH, JERRY, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's rejection of claims 1-17, 19-38 and 43-45, which constitute all the claims remaining in the application.

The disclosed invention pertains to the design of a clinical trial management system.

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Representative claim 1 is reproduced as follows:

A clinical trial management system comprising:

a main database of information concerning prior clinical trials and resources available to conduct future clinical trials, the information concerning prior clinical trials being at least in part in the form of a protocol of (a) scheduled visits of a test subject to a treatment site, (b) measurement of prescribed physical attributes of the subject during the visits and (c) administration of at least one prescribed medical product to the subject during the visit to determine over time the subject's response thereto, the protocol of a prior clinical trial being stored in said main database in the form of a software template;

a main processor controlling access to said main database; and

at least one user processor in communication with said main processor to negotiate access to said main database, said user processor and main processor running a program that designs and tracks at said user processor of a clinical trial through access by said user processor to at least one software template in said main database and modification of the template for formulating a new clinical trial.

The examiner relies on the following references:

Umen et al. (Umen)	5,734,883	Mar. 31, 1998
Edelson et al. (Edelson)	5,737,539	Apr. 07, 1998
Colon et al. (Colon)	5,991,731	Nov. 23, 1999
DeBusk et al. (DeBusk)	5,995,937	Nov. 30, 1999

The following rejections are on appeal before us<sup>1</sup>:

1. Claims 1, 6, 7, 11, 13 and 43 stand rejected under 35

U.S.C. § 103(a) as being unpatentable over the teachings of Colon

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<sup>1</sup> The rejection of claims 35-38 under the second paragraph of 35 U.S.C. § 112 has been withdrawn by the examiner [answer, page 5].

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in view of DeBusk.

2. Claims 2-5, 15-17, 19-24, 28, 32-38 and 44 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the teachings of Colon and DeBusk and further in view of Edelson.

3. Claims 25-27, 29, 30 and 45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the teachings of Colon, DeBusk and Edelson and further in view of Umen.

4. Claims 8-10 and 12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the teachings of Colon and DeBusk and further in view of Umen.

5. Claim 14 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over the teachings of Colon and DeBusk and further in view of Official Notice.

6. Claim 31 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over the teachings of Colon, DeBusk, Edelson and Umen and further in view of Official Notice.

Rather than repeat the arguments of appellants or the examiner, we make reference to the briefs and the answer for the respective details thereof.

OPINION

We have carefully considered the subject matter on appeal, the rejections advanced by the examiner and the evidence

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of obviousness relied upon by the examiner as support for the rejections. We have, likewise, reviewed and taken into consideration, in reaching our decision, the appellants' arguments set forth in the briefs along with the examiner's rationale in support of the rejections and arguments in rebuttal set forth in the examiner's answer.

It is our view, after consideration of the record before us, that the evidence relied upon and the level of skill in the particular art would not have suggested to one of ordinary skill in the art the obviousness of the invention as set forth in the claims on appeal. Accordingly, we reverse.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the examiner to establish a factual basis to support the legal conclusion of obviousness. See In re Fine, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the examiner is expected to make the factual determinations set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), and to provide a reason why one having ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some

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teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986); ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the examiner are an essential part of complying with the burden of presenting a prima facie case of obviousness. Note In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). If that burden is met, the burden then shifts to the applicant to overcome the prima facie case with argument and/or evidence. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. See Id.; In re Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986); In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984); and In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976). Only those arguments actually made by appellants have been considered in this decision. Arguments which appellants could have made but chose

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not to make in the brief have not been considered and are deemed to be waived by appellants [see 37 CFR § 41.37(c)(1)(vii)(2004)].

We consider first the rejection of claims 1, 6, 7, 11, 13 and 43 based on Colon and DeBusk. With respect to independent claim 1, the examiner finds that Colon teaches the claimed invention except that Colon fails to explicitly disclose the protocol of a prior clinical trial being stored in the main database in the form of a software template, the user processor and main processor running a program that designs and tracks at the user processor a clinical trial through access by the user processor to at least one software template in the main database and modification of the template for formulating a new clinical trial or event. The examiner cites DeBusk as teaching these features. The examiner finds that it would have been obvious to the artisan to modify the clinical trial management system of Colon to include these features of DeBusk [answer, pages 5-7].

Appellants argue that neither Colon nor DeBusk teaches or suggests the design of a clinical trial. Appellants assert that Colon relates to the conduct of an already-designed clinical trial whereas DeBusk does not relate to a clinical trial at all.

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Thus, appellants argue that neither applied reference suggests the design of a clinical trial, let alone a critical trial based on templates created from a protocol of tasks to be completed based on old clinical trials as claimed. Appellants argue that the examiner is mistaken in asserting that DeBusk teaches the standardization of a prior clinical trial stored in a database in the form of a software template as recited in claim 1. Appellants also argue that the portions of Colon relied on by the examiner do not at all relate to the standardization of a prior clinical trial being stored in a database as claimed [brief, pages 5-7].

The examiner responds that all of appellants' arguments have been addressed in the rejection. The examiner also asserts that nothing in the language of claim 1 precludes use of the system for an existing clinical trial. The examiner points out again how he reads the language of claim 1 on the applied prior art. The examiner notes that there is no component in the claim language that actually performs the designing, but rather a processor running a program that designs and tracks [answer, pages 27-31].

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Appellants respond that Colon has no information that relates to future clinical trials and DeBusk does not relate to clinical trials at all. Appellants assert that claim 1 requires the creation of a new clinical trial. Appellants essentially reiterate all the arguments which were made in the main brief [reply brief, pages 1-8].

We will not sustain the examiner's rejection of independent claim 1 or of claims 6, 7, 11 and 13 which depend therefrom for essentially the reasons argued by appellants in the briefs. Claim 1 recites inter alia a "program that designs and tracks at said user processor of a clinical trial through access by said user processor to at least one software template in said main database and modification of the template for formulating a new clinical trial." The examiner appears to dismiss this portion of the claim by asserting that there is no component that actually performs this function, however, the claim clearly recites that a computer program within the main processor performs this function. Neither Colon nor DeBusk designs or tracks a clinical trial or modifies a template for formulating a new clinical trial. Despite the examiner's attempts to read the claim language on portions of Colon and DeBusk, we agree with

appellants that the examiner's findings are unsupported by the applied prior art.

With respect to independent claim 43, the examiner has indicated how he finds the claimed invention to be obvious [answer, pages 8-9]. In addition to the arguments considered above, appellants argue that neither Colon nor DeBusk suggests the input of information with regard to completion of tasks and the tracking of the completion of tasks of a clinical trial at a user processor [brief, page 9]. The examiner responds by further explaining how he interprets the claimed invention to be suggested by the applied prior art [answer, pages 34-35]. Appellants respond that the portion of DeBusk cited by the examiner fails to teach or suggest the claimed tracking of preassigned tasks [reply brief, pages 10-11].

We will not sustain the examiner's rejection of independent claim 43 for reasons argued by appellants and for the reasons discussed above with respect to claim 1. Specifically, notwithstanding the examiner's assertions to the contrary, we find no teachings in Colon and DeBusk which relate to a program that designs a clinical trial and tracks the completion of tasks forming a protocol for the clinical trial as claimed.

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We now consider the rejection of independent claim 19 based on Colon, DeBusk and Edelson. Claim 19 contains recitations similar to independent claims 1 and 43. As discussed above, the collective teachings of Colon and DeBusk fail to suggest the obviousness of these recitations. Therefore, Colon and DeBusk do not support the rejection of claim 19 for the same reasons discussed above with respect to claims 1 and 43. Since Edelson does not overcome the deficiencies of Colon and DeBusk, we will not sustain the rejection of independent claim 19 for the same reasons discussed above.

In summary, we have not sustained the rejection of any of independent claims 1, 19 and 43. Since all the remaining claims on appeal depend from one of these independent claims, we do not sustain the rejection of any of the dependent claims for reasons discussed above. We note that the rejection using the additional teachings of Umen fails because Umen does not overcome the

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deficiencies of Colon and DeBusk. Therefore, the decision of the examiner rejecting claims 1-17, 19-38 and 43-45 is reversed.

REVERSED

Jerry Smith

JS/dpv

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